

**INTERNATIONAL PRELIMINARY
 EXAMINATION REPORT – SEPARATE SHEET**

International application Nr PCT/FR03/02252

Concerning point V

**Reasoned statement pursuant with regard to novelty, inventive step and industrial application;
 citations and explanations supporting such statement**

1. Document WO 01/45776 A (D1), which is considered the closest prior art to the subject of claim 1, discloses an injection device with the following features (the reference numerals in brackets apply to this document) (refer to page 8, line 17 – page 9, line 5):

Injection device (10) for a product, in particular for medical use, comprising

- a body (20) receiving a hollow injection needle (60) and a container (37) containing the product to be injected; the needle (60) is connected to the body (20) and is able to move relative to the latter between a position that enables the injection to be performed and a retracted position;
- a plunger (35) is slidably mounted on the body (20) and movable relative to the latter for performing the injection; the container (37) is closed at one end;
- means (22, 34, 42) for keeping the needle (60) in position, which means normally keep the needle (60) in the position that enables the injection to be performed, and can be released to free the needle (60) to move to the retracted position ;
- a piston (30) engaged in the container (37) and so shaped that, in a first configuration of the piston (30) or relative position of this piston (30) and of its container (37), it closes the container (37) in such a way as to isolate the product from the environment outside this container (37) and
- respective means (42), *at the distal end of the plunger (35)*, for operating said means (42) for holding the needle (60) in position and said means for holding the container (37) in position, which, at the end of the injection, release the means (42) for holding the needle (60) in position before, or at the same time as, the means for holding the container (37) in position are released.

The subject matter of claim 1 differs from this known injection device in that

- the container (10) is connected to this plunger (9) and is able to move relative to the latter between a position that enables the injection to be performed and a retracted position;

- means (45, 39, 41) are provided for keeping the container (10) in position, which means normally keep the container (10) in the position that enables the injection to be performed, and can be released to free the container (10) to move to the retracted position ;
- in a second configuration of the piston (11) or relative position of this piston (11) and of this container (10), the piston (11) is configured to allow the product to pass out of the container (10).

The subject of claim 1 is therefore new (Article 33(2) PCT).

It can be considered that the **technical aim** of the present invention is, for an injection device, to increase the reliability of the injection and the safety against risks of accidental pricks.

According to the **solution** suggested in claim 1 of the present patent application, the means (45, 39, 41) for holding the container (10) and the injection needle (4) in position are released at the end of the injection in order to free those two parts (10, 4) from their respective supports so that they may reliably and efficiently retract into the plunger (9).

This solution is not obvious compared to the device disclosed in D1 (see page 8, line 17 – page 9, line 5), because the piston (32) must fulfill two contradictory requirements:

- a) ensure the tightness of the container (37), which necessarily involves a certain amount of friction between the piston (32) and the internal wall of the container (37) ; and
- b) slide freely on the same surface while it moves into its retracted position.

Consequently, the subject of claim 1 complies with the requirements of Article 33(3) PCT.

Claims 2 to 8 are dependent on claim 1 and therefore, as such, also comply with the requirements of the PCT as far as novelty and inventive step are concerned.

2. As set out below, some of the features of the injection device set forth in claim 1 are more useful to specify how to use the device than to clearly define the device in terms of technical features. The limits which are supposed to be defined by these characteristics are not clearly referred to in this claim, contrary to Article 6 PCT.

2.1 The features relating to the method of use are the following:

lines 27-29: " at the end of the injection, release the means for holding the needle 4 in position before, or at the same time as, the means for holding the container 10 in position are released."

2.2 So that one may understand the way the injection device works, the way the piston 11 can be moved in the container 10 needs to be clearly defined.

2.3 Apparently, the means connecting the container 10 to the plunger 9 (see page 8, line 11) are the same as means (45, 39, 41) (see line 17). This is not clear from the definition of the present claim.